



Patient Group Directions

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A practical guide and framework of competencies
for all professionals using patient group directions

Acknowledgements

Editors	John Wright Business Manager - Non-Medical Prescribing Department of Health
Contributors	Gillian Arr-Jones National Pharmacy Advisor Care Quality Commission Angela Bussey PGD Website Pharmacist Editor London and South East Medicines Information Service, Guy's and St Thomas' NHS Foundation Trust Mary Golding Associate Director Community Health Services East & South East England Specialist Pharmacy Services Sandra Wolper Associate Director Community Health Services East & South East England Specialist Pharmacy Services Liz Mellor Clinical Governance Lead Pharmacist Leeds Teaching Hospitals NHS Trust Anne Fittock Non-Medical Prescribing National Advisor National Prescribing Centre
Production	Colin Bowers Web and Publications Officer (Corporate) Merissa Bellew Web and Publications Manager
Published by:	National Prescribing Centre Ground Floor, Building 2000 Vortex Court Enterprise Way Wavertree Technology Park Liverpool L13 1FB Tel No: (0151) 295 8671 Fax No. (0151) 220 4334
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1 Introduction

Patients' needs are at the centre of the NHS. The aim of providing prompt access to high quality care, within safe systems, is a key priority. Delivering effective care that is personal to individuals' needs, providing choice in the way patients are treated and improving access are all key objectives. To achieve patient-focused services, healthcare professionals are finding ways to work more flexibly. One area in which significant changes have happened is the supply, administration and prescribing of medicines.

The preferred way for patients to receive medicines is for prescribers to provide care for individual patients on a one-to-one basis.

The legal framework that covers medicines usage reflects this principle and is based on the traditional model of prescribing by doctors and dentists. Following extension of prescribing responsibilities, a wide range of healthcare professionals including nurses, midwives, pharmacists, optometrists and some allied health professionals, can access additional training to qualify them to prescribe within their competence. This extension of prescribing responsibilities gives organisations more flexibility when designing their services, so that patients can have greater choice and access to high quality prescribing, when and where they need it.

In addition, some long-standing exemptions in medicines legislation allow certain healthcare professionals to obtain, sell, supply and administer medicines in specific circumstances.

See the glossary (**page 32**) for definitions of supply, administration and prescribing.

There are also situations, not covered by these exemptions, where patients may benefit,

without their safety being compromised, from having a medicine supplied and / or administered directly to them by a range of healthcare professionals.

To enable this to happen, independent prescribers can give a documented Patient Specific Direction (PSD), which instructs another healthcare professional to supply or administer a medicine to a specified patient.

Alternatively, a Patient Group Direction (PGD) is a legal mechanism that allows named registered healthcare professionals to supply and / or administer medicines to groups of patients that fit the criteria laid out in the PGD. So a healthcare professional could supply (e.g. provide an inhaler or tablets) and / or administer a medicine (e.g. give an injection or a suppository) directly to a patient without the need for a prescription or an instruction from a prescriber. Using a PGD is not a form of prescribing.

Unlike prescribing, healthcare professionals entitled to work with a PGD require no additional formal qualification. However, for a PGD to be valid, certain criteria must be met, including; the information that it must contain, the patient group that the PGD can be used for and how the PGD itself is drawn up. Organisations also have a responsibility to ensure that only fully competent and trained registered healthcare professionals use PGDs.

"Medicines Matters: a guide to mechanisms for the prescribing, supply and administration of medicines", summarises the mechanisms available to professionals providing medicines to patients:

Medicines Matters - July 2006: Department of Health - Publications
www.dh.gov.uk

1.1 Purpose of this document

The purpose of this document is to:

- Put PGDs into context so individuals and organisations can consider the most appropriate way for patients to receive their medicines
- Be a reference source for registered healthcare professionals and organisations that are using or, thinking about using PGDs, to help ensure that a PGD is the most appropriate mechanism in the particular circumstances
- Provide information and guidance to organisations developing, authorising and using PGDs
- Act as a signpost to other key reference sources and other relevant information
- Present a competency framework for all healthcare professionals entitled to work with PGDs
- Illustrate briefly how the competency framework can be used in practice, for example, to help structure training and development

1.2 Audience for the document

- Individuals and organisations involved in developing and authorising PGDs (e.g. doctors, pharmacists, clinical governance leads)
- All registered healthcare professionals supplying and / or administering medicines to patients
- Managers of all healthcare professionals working with PGDs
- Professional bodies whose members are involved in developing, authorising or working with PGDs
- NHS healthcare commissioners
- Academic establishments training healthcare professionals at undergraduate and postgraduate level

2 How patients receive medicines

Background

The preferred way for patients to receive medicines is for an appropriately qualified healthcare professional to prescribe for an individual patient on a one-to-one basis. The legislation surrounding the use of medicines, which is designed to protect patient safety, was built around this and the traditional model of prescribing. In other words, a doctor (or dentist), assessed a patient and if a medicine was necessary, wrote a prescription: a pharmacist then dispensed the medicine to the patient against that prescription.

Prescribing responsibilities have been expanded to allow specially trained nurses (or midwives), pharmacists and optometrists to train to prescribe independently. These professionals, together with certain allied health professionals, can also work as supplementary prescribers, in partnership with a doctor. For further guidance on the implementation of prescribing by these professional groups see:

**Improving patients' access to medicines:
A guide to implementing nurse and
pharmacist independent prescribing within
the NHS in England - April 2006:**
Department of Health - Publications
www.dh.gov.uk

**Supplementary Prescribing by Nurses,
Pharmacists, Chiropodists/Podiatrists,
Physiotherapists and Radiographers
within the NHS in England: a guide for
implementation - updated May 2005:**
Department of Health - Publications
www.dh.gov.uk

However, in some circumstances it is more convenient for patients to receive their medicines using the other mechanisms available for the supply and/or administration of medicines.

"Medicines Matters: A guide to mechanisms for the prescribing, supply and administration of medicines", summarises the mechanisms available. These can be used by organisations to support the development of new/enhanced roles and redesign of services to best meet the needs of patients and the service. Practitioners and their managers need to select the most appropriate option, depending on the setting and how the service in question is structured. A guide to help organisations choose the best option is available on the PGD website at: www.pgd.nhs.uk/

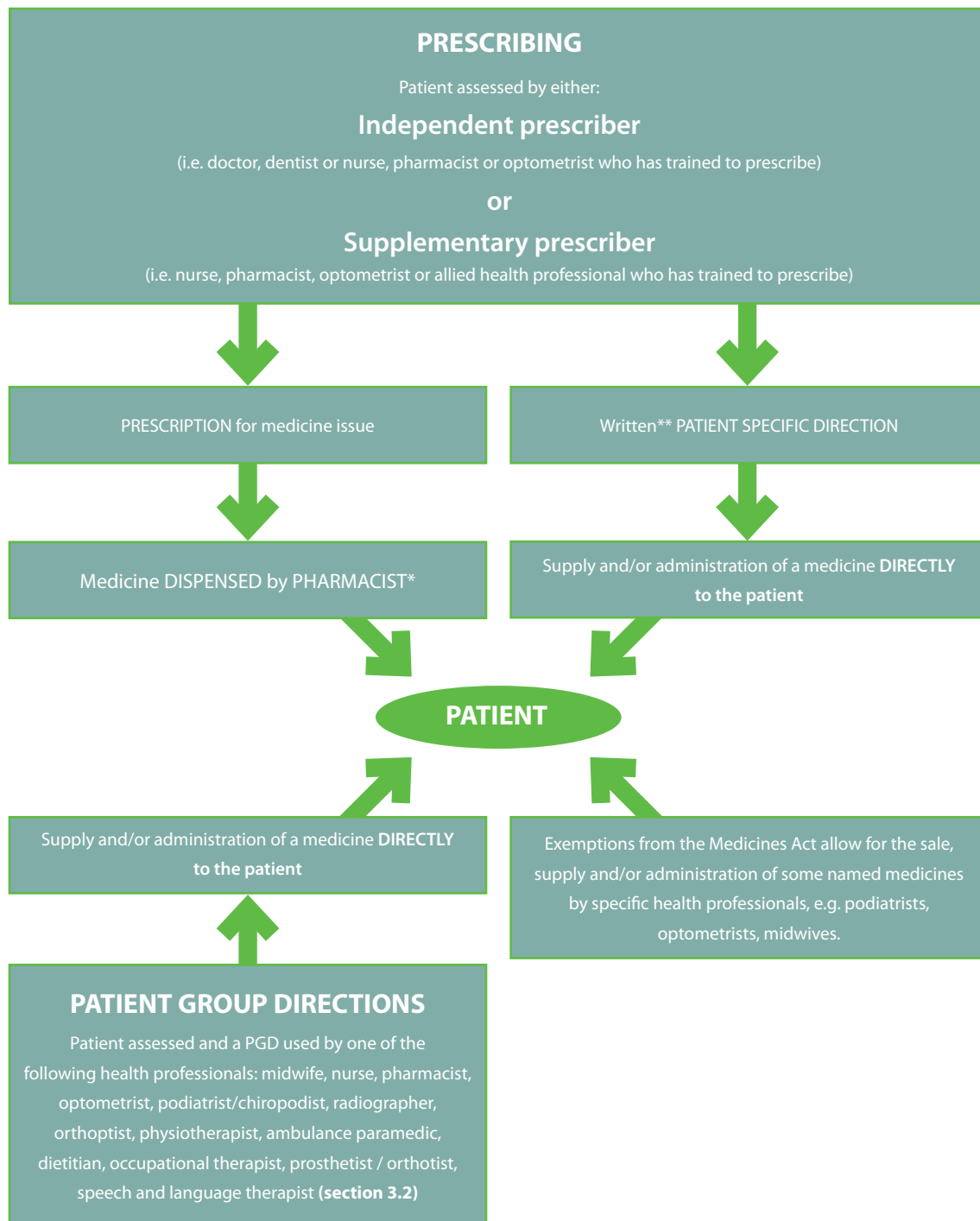
Figure 1 (see overleaf) outlines how the various mechanisms can be used to provide medicines to a patient, according to the circumstances.

Case study 1

An illustration of how the different mechanisms can be used is the prescribing, supply and administration of a flu vaccine in various healthcare settings, in both NHS and independent sectors:

- A community nurse may administer to a patient in their own home. This could be following a prescription and supply of the medicine by a community pharmacy or following a Patient Specific Direction from a GP
- A community pharmacist may administer flu vaccine using a Patient Group Direction as part of an NHS enhanced service
- A community matron may prescribe flu vaccine as a Nurse Independent Prescriber and either administer it themselves or issue a Patient Specific Direction to an individual who is competent to administer the vaccine
- Occupational health schemes may administer flu vaccines under Medicines Act exemptions

Figure 1: How patients receive their medicines.



* In some emergency situations pharmacists are able to supply medicines to patients without a prescription.

For further details see: www.rpsgb.org.uk/Informationresources/: Download Society publications

** this includes directions 'written' electronically

2.1 Legislation governing the use of medicines — the key points

A summary of the legislation governing the use of medicines, together with information about the availability, prescribing, selling and supplying of medicines is available on the Medicines & Healthcare products Regulatory Agency (MHRA) website at:

www.mhra.gov.uk/Howweregulate/Medicines/index.htm

It is important that all professional groups, and their employers, understand the scope and limitations of Patient Group Directions (**see section 3**), as well as the wider context into which they fit when designing safe, effective services for their patients.

The remainder of this section will therefore:

- Highlight the differences between prescribing and the other mechanisms available
- Signpost advice and information about the other mechanisms
- Provide tools and signposting to help services decide which mechanism is best suited to the particular circumstances

2.2 The difference between prescribing and Patient Group Directions

Confusion can arise about the difference between a PGD and the other mechanisms for prescribing, supply and administration of medicines, and which is the most appropriate for the particular circumstances.

When a prescriber sees a patient, and following assessment and diagnosis, decides that a medicine is needed as part of the treatment plan; in the majority of cases, a prescription is issued. A pharmacist then dispenses the

medicine against the prescription and the patient receives their medicine. Medicines law recognises the value of pharmacists in the checking and dispensing process and this is the main route by which patients get their medicines.

However, in some cases, it may be necessary or convenient for a patient to receive a medicine (i.e. have it supplied and / or administered) directly from another healthcare professional. Unless already covered by exemptions to the Medicines Act (**see section 2.3**), there are two ways of achieving this; by PSD or PGD.

A Patient Specific Direction is used once a patient has been assessed by a prescriber and that prescriber, (doctor, dentist or other independent prescriber) instructs another healthcare professional in writing to supply or administer a medicine directly to that named patient or, to several named patients (e.g. patients on a clinic list). A PSD is a direct instruction and does not require an assessment of the patient by the healthcare professional instructed to supply and / or administer, unlike a PGD. It is the responsibility of the person issuing the PSD to ensure that the individual supplying or administering the medicine is competent to do so.

Examples of a service using a Patient Specific Direction:

- An ophthalmologist giving an ophthalmic technician a written Patient Specific Direction to administer anaesthetic eye drops so that, where necessary, the patient has local anaesthesia prior to seeing the ophthalmologist for a scheduled procedure or examination.
- A prescriber e.g. a doctor or Nurse Independent Prescriber writing a PSD on a patient's ward chart
- A GP writing a PSD to instruct a practice nurse to administer goserelin to one of their patients.

A Patient Group Direction allows specified registered healthcare professionals (see section 3.2) to supply and / or administer a medicine directly to a patient with an identified clinical condition without him/her necessarily seeing a prescriber. So, patients may present directly to healthcare professionals using PGDs in their services without seeing a doctor (**as in First contact services — see Case study 2 — and the examples below**). Alternatively, the patient may have been referred by a doctor to another service. Whichever way the patient presents, the healthcare professional working within the PGD is responsible for assessing that the patient fits the criteria set out in the PGD.

In general, a PGD is not meant to be a long-term means of managing a patient's clinical condition. This is best achieved by a healthcare professional prescribing for an individual patient on a one-to-one basis.

Example of services using a PGD:

- An emergency care nurse using a PGD to administer lidocaine to a patient requiring suture of a wound.
- A nurse in a sexual health clinic using a PGD to give patients a supply of azithromycin to treat a Chlamydia infection.
- A community pharmacist using a PGD to give women the contraceptive pill without a prescription.

2.3 Exemptions under the Medicines Act

There are some exemptions to medicines legislation restrictions on the sale, supply and administration of specified medicines for certain groups of healthcare professionals. Some exemptions also allow for the sale and supply of Pharmacy (P) and General Sales List (GSL) medicines. Full details of all these exemptions can be found on the MHRA website at:

www.mhra.gov.uk/howweregulate/medicines/index.htm

In these specific cases PGDs and / or Patient Specific Directions are unnecessary, although organisations may find it helpful to develop local policies or procedures to help ensure safe and effective delivery of care.

2.4 Choosing the most appropriate mechanism

The majority of clinical care should be provided on an individual patient-specific basis. The supply and administration of medicines under PGDs should be reserved for those limited situations where this offers an advantage for patient care without compromising patient safety, and where it is consistent with appropriate professional relationships and accountability.

The decision on whether to use a PGD or one of the other mechanisms will depend on how an individual service is structured. Services in different organisations may choose, because of differences in the way their services are organised, to supply and / or administer medicines to their patients in different ways. For example, doctors referring patients to nurse-led clinics may write a PSD in the patient's notes for the nurse to supply and / or administer a particular medicine. Alternatively, the nurse-led clinic may have several PGDs, which cover the patient groups likely to be seen in the clinic.

For further guidance on deciding whether to use a PGD see 'To PGD or not to PGD – that is the question' and 'Option Appraisal – are PGDs the safest route for your service' on the PGD website at: www.pgd.nhs.uk/

"Medicines Matters: A guide to mechanisms for the prescribing, supply and administration of medicines", also provides advice on how to choose the most appropriate option for providing a patient with a medicine.

2.5 When to use a PGD; when to prescribe

A combination of independent prescribing, supplementary prescribing and PGDs can be used to enable patients to get their medicines. When structuring services it is important to consider which of these options are:

- Legally possible (for example, only specified health professions can train as supplementary prescribers)
- The most appropriate (for example, prescribing is the preferred option for the longer-term management of specific patients)

The case study in **Figure 2** illustrates how independent prescribing, supplementary prescribing and PGDs can be used in the same GP practice to manage patients with asthma. This case study is just one illustration and should not be taken as a model for service delivery.

When deciding whether a PGD is appropriate, every organisation must take account of the needs of the patient, of safety and how the particular service is being structured and delivered. For example:

- Do the conditions and treatments easily fit pre-determined criteria and is there a defined episode of care?
- Is there a need to deliver faster access to treatment without the need for immediate intervention by a prescriber?
- Is use of the medicine in the particular care setting well documented?
- PGDs are not appropriate for the long-term and open-ended supply of medicines

to patients with chronic illness, but they may be used (e.g. for the supply of repeat contraception in family planning clinics).

There might be additional considerations such as the arrangements for wholesale supply of the medicine(s) in question, e.g. for independent sector providers delivering services under contract with NHS organisations. See MHRA guidance on independent companies providing retinal screening services.

www.mhra.gov.uk/howweregulate/medicines/index.htm

In summary, PGDs fit best within services where medicines use follows a predictable pattern and is less individualised. PGDs are generally most appropriate to manage a specific treatment episode (or episodes) where supply and/or administration of a medicine is necessary (**e.g. First contact services — see Case study 2**). As opposed to taking responsibility for managing an individual patient's condition over the long-term, where a prescribing relationship is likely to be more appropriate (e.g. the management of high blood pressure in primary care).

Case study 2

First contact services — ideally suited to PGDs

First contact services are those services through which patients who are acutely unwell first make contact with NHS professionals and seek unscheduled care. They include NHS Walk-in Centres, Community Pharmacies, Minor Injuries Clinics and Out-of-Hours Services, Ambulance Services and Accident and Emergency Services.

PGDs work well for first contact services because many minor illnesses and injuries can be treated successfully with a medicine. PGDs allow certain healthcare professionals working in first contact services to complete a patient's treatment episode without the need to refer to a general practitioner or a hospital doctor for a prescription.

First contact services use Patient Group Directions to cover a range of medicines including:

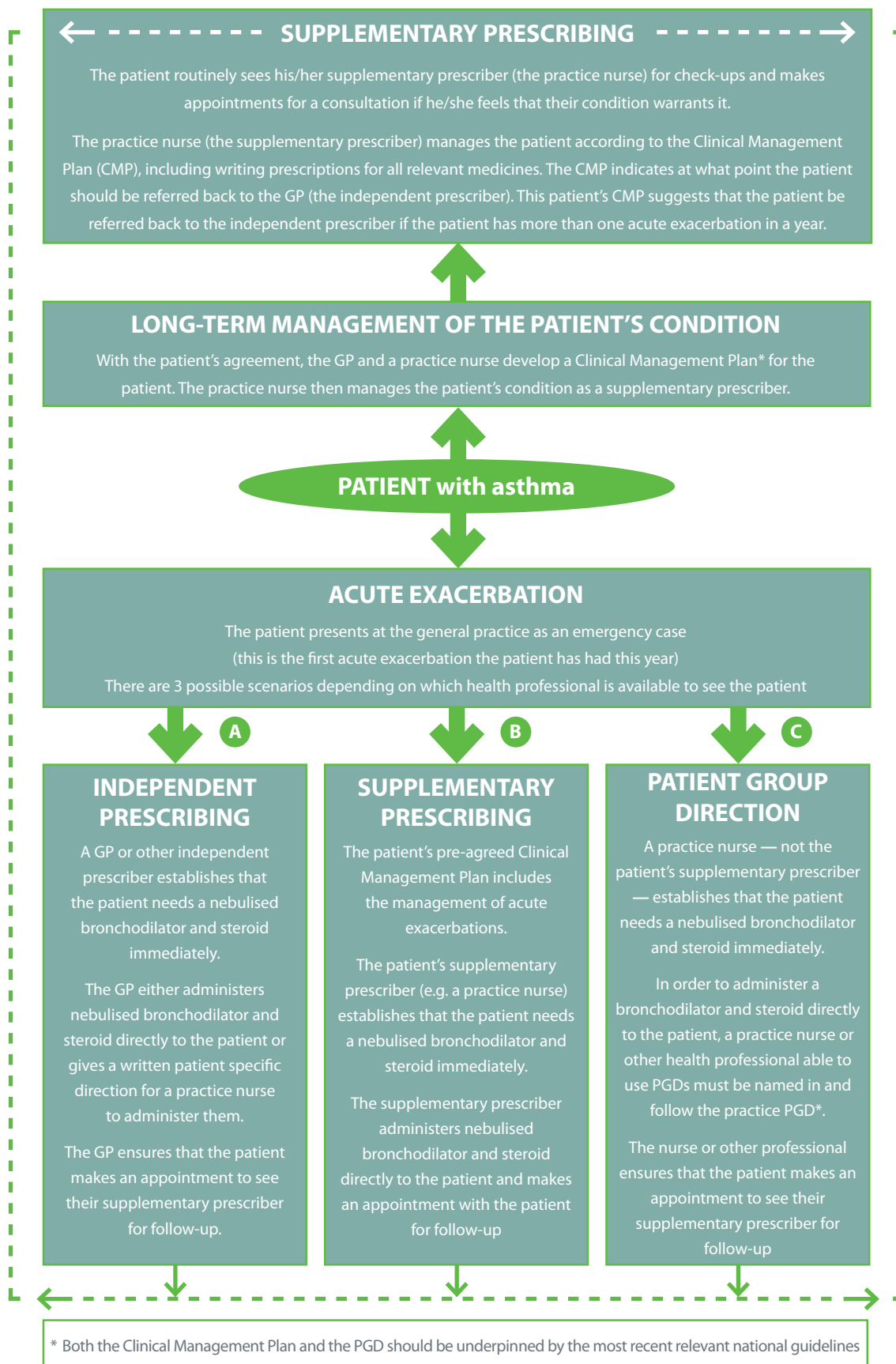
- Trimethoprim for urinary tract infection
- Emergency contraception
- Local anesthesia for suturing a wound
- Analgesia for a range of clinical conditions

Nurses and pharmacists working in first contact services may also be qualified independent prescribers. Nurse and Pharmacist Independent Prescribers are able to issue prescriptions for any licensed medicine to treat conditions within their competence, including for nurses, some controlled drugs. In these cases, some first contact services may issue prescriptions to be dispensed by a pharmacist rather, than use a PGD.

Supplementary prescribing is unlikely to help first contact services because, legally, it requires a partnership between an independent prescriber and an agreed, patient-specific Clinical Management Plan before prescribing can occur. It is not intended for one-off episodes of care.

The PGD website www.pgd.nhs.uk/ has a range of local examples of PGDs used in first contact services.

Figure 2: Case study highlighting how independent prescribing, supplementary prescribing and PGDs can be used to help deliver services to patients



3 Using a PGD

A PGD provides a legal mechanism by which medicines can be supplied and/or administered to patients by a specified range of healthcare professionals, without first seeing a doctor or dentist.

This section focuses on the practical issues around PGD usage and covers:

- The legal definition of a PGD (**section 3.1**)
- Professional groups who can use a PGD (**section 3.2**)
- Organisations that can use a PGD (**section 3.3**)
- Requirements for producing and authorising a PGD (**section 3.4**)
- The information that should be contained in a PGD (**section 3.5**)
- Specific requirements for controlled drugs and antimicrobials (**section 3.6**)
- The law on supply and / or administration of unlicensed medicines and 'off-license' / 'off-label' use, under a PGD (**section 3.7**)

To make this section as practical as possible, case studies will be used to illustrate specific points. Reading this section may give rise to further questions about PGD usage. The Frequently asked questions (FAQs) in **section 4** of this document may help to answer many of these. Further advice and information, including more FAQs and template PGDs, are available on the PGD website at www.pgd.nhs.uk. This is a portal of the National electronic Library for Medicines (NeLM) www.nelm.nhs.uk.

3.1 Definition of a PGD

The legal definition of a PGD is:

'a written instruction for the supply and/or administration of a licensed medicine (or medicines) in an identified clinical situation, signed by a doctor or dentist and a pharmacist.'

It applies to groups of patients who may not be individually identified before presenting for treatment.'

This should not be interpreted as indicating that the patient **must not** be identified; patients within the group may, or may not be known to the service, depending on the circumstances.

In simple terms, a PGD is the supply and/or administration of a specified medicine or medicines, by named authorised health professionals, to a well-defined group of patients requiring treatment for the condition described in the PGD. The health professional must be registered.

The majority of clinical care should be provided on an individual, patient-specific basis. The supply and/or administration of medicines under PGDs should be reserved for those limited situations where this offers an advantage for patient care without compromising patient safety, and where it is consistent with appropriate professional relationships and accountability.

3.2 Professional groups who can use a PGD

A list of the registered health professions able to use PGDs is available on the MHRA website www.mhra.gov.uk.

Professionals using a PGD must be registered (or equivalent) members of their profession and act within their appropriate code of professional conduct. This differs from supplementary prescribers and independent prescribers who must also successfully complete specific prescribing training and be appropriately registered before they may prescribe.

However, organisations using PGDs must designate an appropriate person within the organisation (for example, a clinical supervisor, line manager, General Practitioner) to ensure that only fully competent, qualified and trained healthcare professionals use PGDs. Individual practitioners using a PGD **must** be named (**see also section 3.4**).

Services using PGDs should ensure that appropriate training is available for healthcare professionals using PGDs. **Section 5** of this document presents a competency framework, which can be used by any healthcare professional and their managers to help ensure that he/she has the competencies necessary to work through a PGD.

3.3 Organisations that can use a PGD

PGDs can be used in the NHS, including those services funded by the NHS but provided by the private, voluntary or charitable sector.

In 2003, legislation was passed to allow certain non-NHS organisations to use PGDs for the sale, supply and/or administration of medicines. The organisations outside the NHS able to use PGDs are:

- Independent hospitals, agencies and clinics registered under the Care Standards Act 2000
- Prison healthcare services
- Police services
- Defence medical services

These organisations are advised to follow the same guidance as that issued to the NHS, both in terms of when PGDs can be used and how they should be produced. For a summary of this guidance **see** www.mhra.gov.uk and look for PGDs in the index.

Independent and public sector nursing and care homes are not covered by this later

legislation and so cannot produce PGDs for use within individual or groups of homes.

However, PGDs used by healthcare professionals in their routine practice can be used when visiting patients in nursing and care homes (for example, district nurses, physiotherapists and chiropodists may routinely use PGDs authorised by their organisations on domiciliary visits).

3.4 Producing and authorising a PGD

A PGD should be produced by a multidisciplinary group involving a doctor or dentist, a pharmacist and a representative of any professional group expected to supply and / or administer medicines under the PGD. It is good practice to involve local drug and therapeutic / medicines management committees, area prescribing committees and similar advisory bodies with medicines expertise.

Many NHS organisations have their own local trust-wide policies that describe the process for developing PGDs across their organisation. Some examples of trust wide policies can be found on the PGD website.

A PGD must also be authorised by the organisation in which it is going to be used. In the NHS, this is typically an NHS trust or primary care organisation (for example an NHS PGD for use in a community pharmacy, must be authorised by the local primary care trust). For the most part, it is the clinical governance lead who is likely to authorise a PGD on behalf of these organisations.

Details of the persons by whom or on whose behalf a Patient Group Direction used for the provision of healthcare in NHS and non-NHS settings must be authorised, are available on the MHRA website at www.mhra.gov.uk.

A PGD must be signed by:

- The senior doctor / dentist and senior pharmacist involved in developing the PGD
- The authorising authority for the organisation in which it is being used

For further information on the governance of PGDs in NHS commissioned services and in the private sector, **see the PGD website FAQ section:** www.portal.nelm.nhs.uk/PGD/viewRecord.aspx?recordID=1136&referer

Authorising a PGD to be used in more than one organisation

A PGD can be developed and authorised for use in several organisations (e.g. across several PCTs). In such cases, the following principles may be helpful in ensuring proper authorisation, in order that a PGD can be used by staff employed by one PCT, but delivering care to populations in other PCTs.

- All PGDs must be signed by those responsible for drawing it up, including a doctor or dentist and senior pharmacist. It is good practice for PGDs to be also signed by a senior practitioner from the relevant professional group (e.g. nurse or podiatrist). It does not matter if these signatories are not an employee of the PCT concerned
- An agreed clinical governance lead must sign to authorise any PGD in use for patients within the PCT. This is required in order for the activity to be accepted within the PCT clinical governance framework
- It is acceptable for a PGD to bear more than one PCT logo and be authorised by multiple clinical governance leads, if this is appropriate. The signatures of those responsible for developing the PGD will remain the same
- A PGD for the same clinical activity (e.g. supply of emergency contraceptive

pill in community pharmacies) across several PCTs should contain consistent and identical clinical content, even if minor differences in presentation emerge. This will support practitioners who are likely to move between posts locally (e.g. locum or relief manager community pharmacists)

Before a healthcare professional can use a PGD, he/she must be named and have signed the PGD documentation. This generally takes the form of signatures and names (on a list or individual forms) that are attached to the PGD itself or held by the service or organisation.

Employees of NHS organisations authorising a PGD generally have indemnity attached to their status as an employee. This may also apply to non-NHS organisations. However, the organisations and employees involved should always check that this is the case. If the professional is not directly employed by the organisation, he/she still needs to be assessed as competent to use the PGD and must have his/her own relevant indemnity insurance.

These issues have implications for service delivery, because when new staff begin, or if locum or agency staff are covering services, they may not be able to work under a PGD immediately or, may be excluded because of their employment status. Service managers need to be aware of these issues and plan service delivery to accommodate them.

3.5 Information that should be contained in a PGD

Legislation requires that the following information must be included in a PGD:

- The name of the body to which the direction applies
- The date the direction comes into force and the date it expires
- A description of the medicine(s) to which the direction applies

- The clinical conditions covered by the direction
- A description of those patients excluded from treatment under the direction
- A description of the circumstances under which further advice should be sought from a doctor (or dentist, as appropriate) and arrangements for referral made
- Appropriate dosage and maximum total dosage, quantity, pharmaceutical form and strength, route and frequency of administration, and minimum or maximum period over which the medicine should be administered
- Relevant warnings, including potential adverse reactions
- Details of any follow-up action and the circumstances
- A statement of the records to be kept for audit purposes

A template PGD is available on the PGD website:

www.portal.nelm.nhs.uk/wp/resources/DownloadDoc.aspx?id=563

All PGDs should be underpinned by the best possible evidence-base (e.g. clinical guidelines, consensus statements). These guidelines do not need to form part of the PGD but should be used as a basis for producing it and the PGD should contain the relevant references.

When preparing a PGD, it is best to include only the required content (outlined above). Relevant clinical guidelines can be referenced and included in local clinical protocols or attached as an appendix. PGDs should be reviewed and updated when relevant but if there are changes to clinical practice that do not affect the PGD, there is then the option to update clinical practice without the need to rewrite, reauthorise and re-sign the PGD.

Clearly, if underpinning clinical guidelines do change, healthcare professionals working

under the PGD need to make sure that their practice is updated.

3.6 Requirements for controlled drugs and antimicrobials

Controlled drugs

The Home Office is responsible for legislation governing the use of controlled drugs. The Misuse of Drugs Regulations 2001 govern controlled drugs usage and allow the following controlled drugs to be supplied or administered under a PGD in the circumstances described:

- Diamorphine for treatment of cardiac pain by nurses working in Coronary Care Units and Accident and Emergency departments of hospitals
- Midazolam, which is part of Schedule 3 of the 2001 Regulations
- All drugs listed in Schedule 4 of the 2001 Regulations (mostly benzodiazepines), except anabolic steroids and any drug or preparation which is designed for administration by injection and which is to be used for the purpose of treating a person who is addicted to a drug
- All drugs listed in Schedule 5 of the 2001 Regulations (i.e. low strength opiates such as codeine)

For full details see Home Office Circular 49/2003: www.homeoffice.gov.uk/about-us/publications/home-office-circulars/circulars-2003/049-2003/ Copies of The Misuse of Drugs Regulations 2001 (SI No: 3998 of 2001) can be downloaded from the Office of Public Sector Information website at: www.opsi.gov.uk

Note:

Proposals to expand the range of controlled drugs and the settings in which these can be supplied and / or administered by nurses and pharmacists working under PGDs, have been approved. Amendments to the Home Office's Misuse of Drugs Regulations are required to bring these changes into effect. This guide will be amended once the necessary regulations are in place.

The National Prescribing Centre has developed a guide to good practice in the management of controlled drugs in primary care (England).
www.npc.co.uk/policy/publications/publications.htm?type=%3Acontrolled

Antimicrobials

Department of Health guidance suggests that particular caution should be used when deciding whether to use a PGD for an antimicrobial medicine. Antimicrobial resistance is a public health issue of great concern and care should be taken to ensure that the PGD would not jeopardise any strategy to control increasing resistance. A PGD should not allow the supply and/or administration of a medicine for minor viral diseases that are unaffected by antibiotics, for example, to treat sore throats in the absence of good evidence of bacterial infection.

A local microbiologist or public health specialist with appropriate expertise should be involved in drawing up the PGD. Local drug and therapeutics / medicines management committees or area prescribing committees should ensure that any PGD is consistent with local policies and subject to regular audit. This guidance applies equally to NHS and non-NHS organisations.

3.7 Unlicensed medicines and 'off-license' / 'off-label' use

Before a medicine can be sold in the UK, the product must have a license, called a marketing authorisation. Once licensed, the medicine can be used in the treatment of specific medical conditions. The Summary of Product Characteristics (SPC) describes how the medicine can be used and prescribed.

PGDs can be used to supply and/or administer medicines outside the terms of their SPC (so called 'off-license' or 'off-label' use), provided that such use is supported by evidence and best clinical practice.

Unlicensed medicines cannot be supplied and/or administered under a PGD.

See also section 4 on frequently asked questions.

3.8 Other restrictions

Organisations and professionals should be aware that other legislation may restrict the use of some drugs e.g. abortifacients. The Abortion Act 1967, as amended, requires that a pregnancy may only be terminated by a registered medical practitioner (i.e. a doctor). Therefore, a PGD cannot be used to supply and/or administer abortifacients. **See further guidance on PGD website:**
www.portal.nelm.nhs.uk/PGD/viewRecord.aspx?recordID=1171&referer

4 Frequently asked questions about PGDs

For ease, these frequently asked questions have been grouped so that questions on similar topics are found together. The broad groupings are:

- Uses of PGDs
- Production of PGDs
- Medicines that can be included in PGDs
- Practical issues
- Training and evaluation

More frequently asked questions about PGDs, along with examples of PGDs which have been approved for use in their local areas, are available on the PGD website:

www.pgd.nhs.uk/

Individual professional bodies may also have information sheets and / or frequently asked questions specifically for their members; **see useful links in section 6.**

4.1 Uses of PGDs

- a. Is a PGD appropriate for managing chronic illnesses?
- b. Can a PGD be used to adjust doses of a patient's medication?
- c. Can a PGD be used to initiate treatment for chronic disease?
- d. Can a PGD be used to supply or administer medicines to patients pre-booked into clinics?
- e. If a patient falls slightly outside the criteria for inclusion in a PGD, can professional judgment be used to supply and/or administer a medicine?

a. Is a PGD appropriate for managing chronic illnesses?

General guidance and the legal definition of a PGD (**see section 3.1**) indicate that PGDs

are not meant to replace a health professional prescribing for an individual patient on a one-to-one basis. In general, individual patient prescribing is more appropriate for patients requiring long-term management of their condition (e.g. treating a range of conditions, monitoring the effects of a medicine and of the condition(s)). Many chronic conditions will therefore not be appropriate for treatment using a PGD and another option like supplementary or independent prescribing may be more suitable.

However, there may be some situations in which using a PGD is appropriate for the direct supply and/or administration of a medicine to a patient with a chronic illness (e.g. administration of salbutamol nebulising solution to a patient with an acute exacerbation of asthma), so each case needs to be considered individually.

b. Can a PGD be used to adjust doses of a patient's medication?

Dose adjustment is allowed under a PGD as long as a dosage range is specified in the PGD and the PGD is being used to supply and / or administer a medicine. A PGD does not give a legal framework for healthcare professionals to adjust a dose of medicine already in a patient's possession.

Healthcare professionals may use written protocols to advise patients to adjust the dose of their medication if that is what is required to maintain optimum treatment (e.g. a diabetes nurse specialist advising a patient to alter insulin dose following a blood glucose check). Written protocols have no legal standing in respect of medicines legislation and are subject to local agreements between healthcare professionals and their organisations — this would include the clinical governance and local authorisation of such procedures/local guidelines to ensure that they comply with organisational systems.

It is likely that written protocols covering advice on dosage would reflect many of the principles governing PGDs.

c. Can a PGD be used to initiate treatment for chronic disease?

Although this is possible within the legislation and supporting guidance, it is not recommended. Chronic conditions should be managed by healthcare professionals prescribing for individual patients on a one-to-one basis.

There may be occasions, however, when a professional e.g. in a Walk-in Centre, treats someone under a PGD for symptoms arising from a chronic disease. This highlights the importance of including clear advice on referral of patients (in this case, to their usual prescriber or professional responsible for their longer-term care) and any other follow-up action required.

d. Can a PGD be used to supply and/or administer medicines to patients pre-booked into clinics?

Pre-booked patients, and therefore 'knowing' who the patient will be, do not preclude PGD use, assuming all other criteria for the use of PGDs are met.

e. If a patient falls slightly outside the criteria for inclusion in the PGD, can professional judgment be used to supply and/or administer a medicine?

No, when supplying and/or administering a medicine under a PGD, the patient must fall exactly into the criteria determined by the PGD. If not, the patient must be referred, in line with the guidelines in the PGD.

4.2 Production of a PGD — see also section 3.4

- a) It has been agreed that a PGD is needed, what procedures should be followed to develop it?

- b) How often should a PGD be reviewed?
c) How long should PGD documentation be kept?
d) Who is responsible for finding and updating the clinical guidelines underpinning a PGD?
e) When changes are made to a PGD, does it always need to be reauthorised and re-signed?

a. It has been agreed that a PGD is needed, what procedures should be followed to develop it?

It is important to ensure that a PGD is the most appropriate mechanism for delivery of the service in question and that all the options have been considered. Tools and resources to help with decision-making are available on the PGD website at:

www.pgd.nhs.uk/SO_YOU_THINK_YOU_NEED_A_PGD_final.pdf

And

www.portal.nelm.nhs.uk/PGD/viewRecord.aspx?recordID=422

Guidance on producing and authorising a PGD is also provided in **section 3.4** of this document

b. How often should a PGD be reviewed?

PGDs should be formally reviewed and reauthorised every two years, and the expiry date must be included in the PGD (**see also section 3.5**); after the expiry date, the PGD is no longer valid. However, the content of the PGD should be reviewed immediately if there are evidence-based changes to clinical practice that affect the PGD, regardless of the expiry date. In practice, some organisations set a review date at least six months before a final expiry date, to allow time for the review process. Organisations should consider auditing the use of PGDs in advance of the review.

c. How long should PGD documentation be kept, i.e. master authorised copy of the PGD, lists of authorised practitioners and patient supply/administration records?

The same rules apply to PGD records as to all other patient records. For adults, all PGD documentation must be kept for eight years, and for children until the child is 25 years old, or for eight years after a child's death.

In addition to patient records relating to the PGD, local arrangements should be in place to retain the master copies of the PGD, lists of authorised practitioners and records of version numbers.

d. Who is responsible for implementing and updating the clinical guidelines underpinning a PGD?

It is up to the individual organisation / service (e.g. Walk-In Centre, GP practice, community pharmacy) using the PGD to implement and update the clinical guidelines underpinning the PGD. The primary care trust or NHS trust authorising the PGD is responsible for ensuring that PGDs satisfy the legal framework in which they can be used, but not for finding / developing and evaluating the underpinning clinical content.

NHS organisations commissioning services from private or voluntary providers should ensure (e.g. by specifying in the contract) that any such providers understand their own responsibilities, particularly to ensure that their employees are working to current best clinical practice.

Further advice about commissioning NHS services from private or voluntary providers is available on the PGD website at:

www.portal.nelm.nhs.uk/pgd/viewRecord.aspx?recordID=961&referer

e. When changes are made to a PGD, does it always need to be reauthorised and re-signed?

Yes (**see section 3.5**), even "minor" amendments require a PGD to be reauthorised. Even where review of a PGD results in no changes, it should still be reauthorized.

The process for review and reauthorisation should be described in the local PGD policy and procedure. Local arrangements should be in place to ensure that all healthcare professionals working under a PGD are made aware of significant changes.

4.3 Medicines that can be included in a PGD —

see also section 3.6, 3.7 and 3.8

- a) Can more than one medicine be included in a PGD?
- b) Can patients receive black triangle (▼) medicines under a PGD?
- c) Can patients receive medicines when they are used outside their licensed uses?
- d) Can patients receive unlicensed medicines under a PGD?
- e) Can patients receive controlled drugs under a PGD?
- f) Can appliances and dressings be supplied and administered under a PGD?

a. Can more than one medicine be included in a PGD?

Generally, it is better to have a PGD for a single medicine, as it helps with audit and monitoring. More than one medicine can be included, but all requirements of the legislation must be included for each drug.

The PGD website has a few examples of PGDs for more than one medicine:

www.portal.nelm.nhs.uk/pgd/viewRecord.aspx?recordID=693&referer

b. Can patients receive black triangle (▼) medicines under a PGD?

Yes, black triangle medicines (i.e. those recently licensed and so subject to special reporting procedures for adverse reactions) may be included in a PGD, provided such use is supported by best clinical practice. The PGD should state that a black triangle medicine is being included and should refer to any supporting guidelines/written evidence,

(e.g. Joint Committee on Vaccination and Immunisation (JCVI) advice).

c. Can patients receive medicines when they are used outside their licensed uses?

Yes, medicines can be used outside the terms of their Summary of Product Characteristics (SPC) (and so outside their license), provided such use is supported by evidence and best clinical practice. This is also called “off-label” or “off-license” use. The PGD should clearly state when the product is being used outside the terms of the SPC and why this use is necessary.

Note: other guidance may dictate that off-label use of a medicine under a PGD is not appropriate, e.g. MHRA statement on supply and administration of Botox, Vistabel, Dysport and other injectable medicines in cosmetic procedures www.mhra.gov.uk/home/idcplg?IdcService=SS_GET_PAGE&nodeId=156

d. Can patients receive unlicensed medicines under a PGD?

No, the PGD framework does not allow for unlicensed medicines to be supplied and / or administered.

For example, imported medicines (e.g. licensed in Europe but not the UK) cannot be supplied or administered under a PGD. The Mantoux test (SSI) is currently imported (as at November 2009) and must be prescribed, or specified using a Patient Specific Direction.

The MHRA has advised that where two separate products are mixed together and one of them cannot be described as a vehicle for the administration of the other (for example as a diluting agent), this results in a new, unlicensed product. Therefore, a PGD cannot be used for mixing of two licensed medicines, unless one is an agent for the other, such as water for injection. See the frequently asked question on the PGD website: www.portal.nelm.nhs.uk/PGD/viewRecord.aspx?recordID=885&referer

e. Can patients receive controlled drugs under a PGD?

Certain controlled drugs can be supplied or administered under a PGD (see section 3.6 or MHRA website: www.mhra.gov.uk)

f. Can appliances and dressings be supplied and/or administered under a PGD?

No, PGDs apply only to licensed medicines. For dressings and appliances, consider using a protocol or guidelines.

Although not legally required, NHS organisations may make a clinical governance decision to develop a PGD for a medical device, where that device contains a medicinal product, e.g. pre-filled syringe of sodium chloride 0.9%, where a risk assessment of the use of the device has identified the need for a PGD.

4.4 Practical issues of usage

- Where can the medicines supplied and administered be obtained from?
- What are the requirements for safe handling, packaging and labelling of medicines?
- Should all patients be given information leaflets with any medicine supplied?
- If not included in existing exemptions to the Medicines Act, is a PGD required for the supply of P and GSL medicines?
- Can PGDs be used to supply and / or administer medicines to patients in their homes or in more than one location?
- Can one PGD be used across multiple organisations?
- Can agency and bank staff working in the NHS use PGDs?
- Do the current exemptions that allow midwives, ambulance paramedics, optometrists, and podiatrists / chiropodists to supply and / or administer certain named medicines without the directions of a doctor, mean that a PGD is not required?
- Do patients receiving medicines under a PGD pay NHS prescription charges?

a. Where can the medicines supplied and administered be obtained from?

Local hospitals, community pharmacies and pre-packing units can all supply medicines; however, appropriate licences may be required.

The wholesale supply of medicines is regulated under medicines legislation and is in general restricted to specified classes of person. NHS organisations entering into arrangements with a private company to provide a service and health professionals setting up their own private service, will need to consider arrangements for obtaining stocks of medicines.

b. What are the requirements for safe handling, packaging and labelling of medicines?

The pharmacist co-author of the PGD will be able to advise on requirements for the safe and secure handling of medicines, as well as packaging and labelling requirements. If a medicine is going to be supplied to the patient to take home, the availability and / or suitability of an appropriately labelled pack will need to be taken into account. Original packs are preferred, where available, and appropriate audit trails should always be in place. The Royal Pharmaceutical Society of Great Britain (RPSGB) fact sheet on PGDs provides further information:

www.rpsgb.org/informationresources/advisoryservices/legalandethicaladvisoryservice/#fact

c. Should all patients be given information leaflets with any medicine supplied?

Yes, when a medicine is supplied on prescription or via a Patient Group Direction it must legally be accompanied by the statutory patient information leaflet – even in cases where the product is being used “off-label”. When a medicine is administered, it is good practice to provide the leaflet to the patient / carer at the time of administration, although this is not a legal requirement.

There are various sources of patient information leaflets. The pharmacist co-author of the PGD should be able to advise on the most suitable information under the circumstances.

d. If a medicine is not included in existing exemptions to the Medicines Act, is a PGD required for the supply of P and GSL medicines?

Medicines legislation states that a PGD is not necessary to supply a General Sales List medicine, provided the supply takes place from lockable premises and the medicines are pre-packed and fully labelled. For organisations supplying GSL medicines in this way, good practice (from a clinical governance perspective) is to use a simple protocol; simple protocols are not part of medicines legislation. A PGD is necessary to supply P medicines, unless the supply is being made at a registered pharmacy by or under the supervision of a pharmacist.

e. Can a PGD be used to supply and/or administer medicines to patients in their homes or in more than one location?

Yes, the PGD need not relate to specific premises. All the requirements that have been specified for a PGD must be complied with, but the supply or administration could take place at a variety of locations including a patient’s home, a surgery or health centre, a pharmacy or an NHS Walk-in Centre.

f. Can one PGD be used across multiple organisations?

Yes, **see section 3.4** for more details.

g. Can agency and bank staff working in the NHS use PGDs?

Any eligible professional using a PGD must be named and assessed as competent to do so (**see sections 3.2 and 3.4**) before they can use one.

Bank staff may be indemnified by the NHS organisation they are working for, but agency staff will need their own indemnity cover.

h. Do the current exemptions that allow midwives, ambulance paramedics, optometrists, and chiropodists/podiatrists to supply and / or administer certain named medicines without the directions of a doctor, mean that a PGD is not required?

Yes, where exemptions for a named medicine exist, PGDs are not necessary and in some cases may hinder existing practice. See **sections 2 and 3.3**, "Medicines, Ethics and Practice: A guide for pharmacists and pharmacy technicians" www.rpsgb.org.uk, and "Medicines Matters: A guide to mechanisms for the prescribing, supply and administration of medicines" for further details and guidance.

i. Do patients receiving medicines under a PGD pay NHS prescription charges?

Standard prescription charge rules and exemptions also apply to all patients receiving a supply of medicines under a PGD from the NHS. Services supplying medicines under a PGD need to arrange for collection of the appropriate fees. If all the medicine is administered to the patient during the consultation, no charge is levied. If any part of the medicine is given to the patient to take home, the patient should be charged. For convenience, some NHS Walk-in Centres have introduced systems that avoid healthcare professionals collecting the charges themselves. Examples include arranging for finance departments to invoice patients following treatment and installing pay machines which issue tokens with which patients 'pay' their prescription charges.

4.5 Training and evaluation

a) What clinical governance and audit procedures should be in place to monitor PGDs?

- b) Who is responsible for ensuring the competence of the healthcare professionals supplying and/or administering medicines using a PGD?
- c) Who is responsible for ensuring the competence of the healthcare professionals developing and authorising a PGD?
- d) Are there any national training programmes for healthcare professionals using PGDs?

a. What clinical governance and audit procedures should be in place to monitor a PGD?

Clinical governance and audit surrounding PGD use are local responsibilities. There are no standard national arrangements. Local organisations should undertake regular audit of PGD use; for example, prior to reauthorising a PGD.

The PGD website www.pgd.nhs.uk contains resources to support organisations with audit.

b. Who is responsible for ensuring the competence of the healthcare professionals supplying and/or administering medicines using PGDs?

Organisations using PGDs must designate an appropriate person within the organisation (for example, a clinical supervisor, line manager, GP) to ensure that only fully competent, qualified and trained healthcare professionals operate within a PGD; where a range of healthcare professionals are using PGDs, this may be a senior representative from each of the professions. There is no current specific national training and development programme for healthcare professionals using PGDs. However, the competency framework in **section 5** of this document can be used as a starting point to help organisations develop their own programmes.

c. Who is responsible for ensuring the competence of the healthcare professionals developing and authorising PGDs?

Organisations should ensure that individuals writing and authorising PGDs have the appropriate competencies to do so; the healthcare professionals writing and authorising the PGDs might not be the ones working under them. There is no specific national training for healthcare professionals producing PGDs. **Section 5** provides general advice on the knowledge and experience that those responsible for developing / authorising PGDs should have and many of the competencies in the main framework will be relevant.

A suitably competent and experienced healthcare professional who will be working under the PGD should be involved in the writing of the PGD, to ensure that the PGD meets the needs of the service.

d. Are there any national training programmes for healthcare professionals using PGDs?

There is no national curriculum for training to use and develop PGDs. Many organisations and services have developed training programmes to meet their own needs. The competency framework in **section 5** of this document provides a starting point for developing training and development programmes.

Links to examples of local training resources and the Centre for Postgraduate Pharmacy Education's Open Learning Pack for PGDs, are available in the training and competency area of the PGD website.

5 Competency framework for healthcare professionals using PGDs

Introduction

The use of PGDs is widespread throughout the NHS and, since April 2003, some non-NHS organisations have been able to use them. Organisations must ensure that staff responsible for the development / implementation of PGDs and those authorised to work under PGDs have the experience, knowledge and skills necessary to do so. Unlike supplementary prescribers and nurse independent prescribers, healthcare professionals using PGDs do not have to become specifically qualified to do so but they must be assessed by their organisations as fully competent, qualified and trained to operate within a PGD (**see section 3.4**).

Table 1 provides guidance on the knowledge and experience that those responsible for the development, authorisation and implementation of PGDs should have, in order to carry out this role.

Table 2 provides an outline framework of competencies that, if acquired and maintained, should help healthcare professionals work safely and effectively with PGDs. Because it is an outline framework, it can be used as a starting point for discussion of competencies required by all healthcare professionals using PGDs. Some of the competencies may be more relevant to some healthcare professionals than others.

A competency is a quality or characteristic of a person, which is related to effective or superior performance.

Competencies can be described as knowledge, skills, motives and personal traits. Competencies help individuals (and their managers) to look at how they do their jobs. A competency framework is a collection of those competencies that are thought to be central to effective performance. Development of competencies should help individuals to improve their performance continually and to work more effectively.

The methodology used to develop this competency framework for healthcare professionals working with PGDs is consistent with that used to develop the competency frameworks for independent and supplementary prescribers. The competencies for working with PGDs are therefore structured and used in the same way. Professionals using PGDs who are also, or may become, independent or supplementary prescribers will benefit from using these complementary competency frameworks.

Details of the development methodology are outlined in all of the existing framework documents; they can be found on the National Prescribing Centre website www.npc.co.uk.

Key point

The framework contains NINE competencies. For ease, these have been grouped into three areas, with three competencies in each area.

The structure of the framework

This competency framework for healthcare professionals working with PGDs is made up of the following components:

- There are three areas of competency in the framework:
 - The consultation
 - Effective supply and/or administration using a PGD
 - PGDs in context

- Each of these three areas contains three competencies. This framework therefore consists of NINE different competencies
- Each of the nine competencies has:
 - An overarching statement which gives a general flavour of what the competency is about
 - A number of statements which represent how healthcare professionals with that competency will be working in practice

This outline structure is illustrated in **Figure 3**.

Table 1: DEVELOPMENT AND AUTHORISATION OF PATIENT GROUP DIRECTIONS

Suggested knowledge and experience required by staff developing / implementing PGDs:

- an understanding of the service where the PGD is to be used and how it operates
- knowledge and understanding of the legal frameworks relating to PGDs
- an understanding of the importance of robust medicines management systems supporting the use of PGDs e.g. storage, labelling and procurement
- an understanding of document and version control
- the ability to make judgments about the content of the PGD
- experience of writing the clinical content of PGDs with evidence of ability to interpret and utilise relevant medicines information (e.g. SPC) for inclusion in the clinical content of the PGD
- experience of working with a multidisciplinary group on the development and implementation of PGDs
- evidence of training/education undertaken about PGDs e.g. CPPE/ PGD study day

Suggested knowledge / experience required by a clinical governance signatory of a PGD:

- an understanding of the service
- knowledge and understanding of the organisation's clinical governance framework and processes
- experience of working with a medicines management group / drug and therapeutics committee or equivalent
- knowledge and understanding of primary medicines legislation and the legal frameworks relating to PGDs

Note: This list is not a complete person specification and organisations are responsible for ensuring that the signatory has adequate skills and experience to carry out this role.

Figure 3: Basic structure of the competency framework

THE CONSULTATION		
1 Clinical and pharmaceutical knowledge	2 Establishing options	3 Communicating with patients
EFFECTIVE SUPPLY AND ADMINISTRATION WITHIN A PGD		
4 Safe PGD use	5 Professional standards	6 Practice development
PGDs IN CONTEXT		
7 Information in context	8 The NHS in context	9 The team and individual context

Key point

Before using the competency framework (Table 2) read these key features. They will help you interpret this multidisciplinary framework.

Key features of the framework

- This framework is an outline framework which can be used by ALL healthcare professionals working with PGDs regardless of the area in which they are practising
- All nine competencies will be relevant to all healthcare professionals. However, some of the statements supporting the competencies will be more relevant to some healthcare professionals than others
- The framework should therefore be used as a starting point for discussion about the competencies required by individual healthcare professionals working with PGDs
- Initially, using this framework effectively will take time. How each of the statements supporting the nine competencies applies to individuals (or groups of healthcare professionals) must be considered
- When considering these statements, be aware that some are more complex than others. Expect to spend more time on the more complex statements
- The bullet pointed statements in each competency should be read one after another DOWN the list. DO NOT read across competency boxes.

Table 2: THE CONSULTATION		
1 CLINICAL AND PHARMACEUTICAL KNOWLEDGE	2 ESTABLISHING OPTIONS	3 COMMUNICATING WITH PATIENTS (parents, carers and advocates where appropriate)
Has up-to-date clinical and pharmaceutical knowledge relevant to the scope of the PGD.	Makes and / or reviews diagnosis and generates treatment options for the patient, including follow-up within the PGD.	Establishes a relationship based on trust and mutual respect. Sees patients as partners in the consultation. Applies the principles of concordance.
<ul style="list-style-type: none"> • Understands the medical conditions being treated, their natural progress and how to assess the severity of disease • Understands different non-pharmacological and pharmacological approaches to modifying disease and promoting health, desirable and undesirable outcomes and how to identify and assess them • Understands the mode of action and pharmacokinetics of medicines and how these mechanisms may be altered (e.g. by age, renal impairment) • Understands the potential for unwanted effects (e.g. adverse drug reactions [ADRs], drug interactions, special precautions and contraindications) and how to avoid / minimise and manage them • Maintains an up-to-date knowledge of products contained in the PGD • Understands how medicines are licensed, supplied and monitored (e.g. ADR reporting) • Applies the principles of evidence-based medicine, and clinical and cost-effectiveness • Understands the public health issues related to medicines use (e.g. antimicrobial drug resistance) • Appreciates the misuse potential of drugs 	<ul style="list-style-type: none"> • Takes a comprehensive medical history and undertakes an appropriate physical examination • Makes and / or reviews a working or final diagnosis by considering and systematically deciding between the various possibilities (differential diagnosis) • Requests and interprets relevant diagnostic tests • Views and assesses the patient's needs holistically (psychosocial, physical) • Considers no treatment, non-drug and drug treatment options (including referral and preventative measures) • Assesses the effect of multiple pathologies, existing medication and contraindications on treatment options • Assesses the risks and benefits to the patient of taking / not taking a medicine (or using / not using a treatment) • Selects the most appropriate PGD for the individual patient • Selects the most appropriate drug, dose and formulation according to the PGD • Identifies on going treatment plan and referral options for patient 	<ul style="list-style-type: none"> • Listens to and understands patients' beliefs and expectations • Understands the cultural, linguistic and religious implications of supplying and administering medicines • Deals sensitively with patients' emotions and concerns • Adapts the consultation to meet the needs of different patients (e.g. for age, level of understanding) • Creates a relationship which does not encourage the expectation that a medicine will be supplied and / or administered • Explains the nature of the patient's condition and the rationale behind, and potential risks and benefits of treatment options • Helps patients to make informed choices about their options • Negotiates an outcome of the consultation that both patient and healthcare professional are satisfied with • Encourages patients to take responsibility for their own health and self-manage their conditions • Identifies opportunities to discuss health promotion with patients • Gives clear instructions to the patient about their medication (e.g. what it is for, how to take it, possible side effects and expected outcomes) • Checks patients' understanding of, and commitment to, their treatment

EFFECTIVE SUPPLY AND ADMINISTRATION WITHIN A PGD		
4 SAFE PGD USE	5 PROFESSIONAL STANDARDS	6 PRACTICE DEVELOPMENT
Is aware of own limitations. Does not compromise patient safety.	Works within professional and organisational standards.	Actively participates in the review and development of practice to improve patient care.
<ul style="list-style-type: none"> • Knows the limits of own knowledge and skill, and works within them • Knows when to refer to, or seek guidance from, another member of the team or a specialist • Supplies and administers a medicine only with adequate, up-to-date knowledge of its actions, indications, contraindications, cautions, dose and side-effects • Checks doses and calculations to ensure accuracy and safety • Knows about common types of medication errors and how to prevent them • Uses PGDs often enough to maintain confidence and competence • Understands the need for, and makes, accurate, clear and timely records and clinical notes 	<ul style="list-style-type: none"> • Accepts personal responsibility for working within PGDs and understands the legal implications of doing so • Understands and works within the scope of the PGD • Makes ethical and / or clinical decisions based on the needs of patients, not personal considerations • Understands current medicines legislation, the legal framework for working with PGDs and how they apply in practice • Applies current professional codes of practice to the use of PGDs • Keeps up-to-date with advances in practice and any emerging safety concerns related to medicines in the PGD • Understands how consent relates to PGDs • Knows how and when PGDs need to be changed; affects necessary changes 	<ul style="list-style-type: none"> • Reflects on own performance, learns and changes practice • Willing to share and debate own, and others' practice • Challenges inappropriate practice constructively • Develops own networks for support, reflection and learning • Develops and uses tools to review and improve PGDs and their use in practice (e.g. audit) • Reviews and reports incidents and near misses within a clinical governance context • Establishes professional links with practitioners working in the same specialist area

PGDs IN CONTEXT		
7 INFORMATION IN CONTEXT	8 THE NHS IN CONTEXT*	9 THE TEAM AND INDIVIDUAL CONTEXT
Knows how to access relevant information. Can critically appraise and apply information in practice.	Understands, and works with, local and national policies and services that impact on PGD use.	Works in partnership with colleagues for the benefit of patients. Is self-aware and confident in own ability to use PGDs.
<ul style="list-style-type: none"> • Understands the advantages and limitations of different information sources • Uses relevant, up-to-date information; both written (paper / electronic) and verbal • Critically appraises the validity of information (e.g. promotional literature, research reports) when necessary • Applies information to the clinical context (linking theory to practice) • Uses relevant patient record systems, information systems, and decision support tools 	<ul style="list-style-type: none"> • Works within local frameworks for medicines use as appropriate (e.g. formularies, protocols and guidelines supporting PGDs) • Works within the NHS / organisational codes of conduct when dealing with the pharmaceutical industry • Understands drug budgetary constraints at local and national levels; can discuss them with colleagues and patients • Understands the national NHS frameworks underpinning PGDs (e.g. National Institute for Health and Clinical Excellence, National Service Frameworks, medicines management, clinical governance) • Legally and safely orders, receives, stores and labels medicines being supplied or administered within a PGD • Understands and levies appropriate prescription charges 	<ul style="list-style-type: none"> • Ensures that continuity of care is not compromised, by keeping all relevant colleagues informed • Uses the multidisciplinary team to its full extent • Establishes relationships with colleagues based on understanding of, and respect for, each others' roles • Recognises and deals with pressures that result in inappropriate use of PGDs • Is adaptable, flexible and responsive to change • Negotiates the appropriate level of support to enable the use of PGDs • Provides support and / or advice to other healthcare professionals where appropriate
<p>* This competency has an NHS focus, however, the principles underpinning several of the statements still apply to health professionals working in non-NHS organisations</p>		

Using the competency framework

The competency framework contains the competencies that all healthcare professionals should either already have or should seek to develop when working with PGDs. The framework is relevant to all healthcare professionals and is an extremely flexible tool that can be used both by individuals and by organisations.

When using the competency framework, the nine competencies it contains need to be applied locally to each professional and / or professional group working with PGDs. This is because healthcare professionals have different skills and experience and use a wide range of medicines using PGDs.

Once the framework has been applied locally, it can be used to support many activities. It can:

- Help individuals and organisations identify training needs
- Assist in the development of training and development programmes
- Facilitate individual continuing professional development
- Facilitate the development of personal development plans
- Help with individual performance review and appraisal systems
- Help with recruitment

To facilitate application of the competency framework by individuals and organisations, a downloadable toolkit is available which contains the framework, along with a blank template version to allow for tailoring of the framework to meet individual needs
see www.npc.co.uk/prescribers.

Some organisations may already have systems in place for many of these uses and the framework can be easily mapped into

these existing systems to ensure that all the competencies are being covered.

Extensive guidance on how to apply and use the competency framework for all these activities is outside the scope of this document. However, some brief examples have been included to give an idea of how the framework might be used:

- By organisations as an aid to training and development
- By individuals for their own continuing professional development

Using the competency framework in training and development

Most organisations will already have some sort of training and development programme for healthcare professionals using PGDs. The competency framework can be used as an aid to any of these programmes in a number of ways:

- To audit existing training and development programmes to ensure that all relevant competencies are being covered
- As a self-assessment tool for healthcare professionals to evaluate their own level of competency before beginning a training and development programme
- To link existing training and development with specific competencies so that healthcare professionals can see how the competencies link to training and development activities
- To provide an ongoing way of structuring continuing professional development

Using the PGD framework to facilitate individual continuing professional development

The framework provides an excellent tool to help individuals assess their own practice when using PGDs. This sort of competency framework has already been used by Nurse Independent Prescribers. Here are some hints from nurse prescribers who have already used it:

- Think of the framework as a way of guiding your reflections on your practice
- Think about using it in a variety of settings to suit your needs, for example, it may be used alone, in a peer group or with your clinical lead
- The framework contains a lot of information. You might find it easier to work through it gradually, one section at a time or one competency at a time
- Remember there are only nine different competencies, so try not to get overwhelmed
- If it helps, download a copy of the framework along with a blank template with space for notes against each competency (**see Table 2**)

6 Useful links

Useful information about PGDs

Resources on the national PGD website (England) www.portal.nelm.nhs.uk/pgd

- Decision making tools
- Signposting to key national resources
- Local PGD examples
- Local PGD Policies and guidelines
- Signposting to national templates
- Frequently asked questions
- Discussion Board
- Enquiry answering service via the "Contact Us" email address.

The Medicines and Healthcare products Regulatory Agency (MHRA) has issued guidance for both NHS and private organisations wishing to use PGDs. Look for PGDs in the sitemap / index www.mhra.gov.uk

The Royal Pharmaceutical Society of Great Britain (RPSGB) has produced a comprehensive PGD fact sheet for pharmacists www.rpsgb.org/informationresources/advisoryservices/legalandethicaladvisoryservice/#fact

The Royal College of Nursing (RCN) has produced "PGDs, guidance and information for nurses" www.rcn.org.uk/__data/assets/pdf_file/0008/78506/001370.pdf

Other useful websites

National electronic Library of Medicines (NeLM) www.nelm.nhs.uk

NeLM is one of the largest medicines information portal for healthcare professionals in the UK National Health Service (NHS). It aims to promote the safe, effective and efficient use of medicines.

The site has a wide range of information products, including news, evidence-based reviews on drugs and drug therapy and health promotion material. It also supports community areas such as Non-Medical Prescribing and Primary/Community Care.

Competency frameworks for nurse independent prescribers, and nurse and pharmacist supplementary prescribers already exist. They can be found on the NPC website: www.npc.co.uk/prescribers

The national network of medicines information pharmacists has detailed guidance about how to use its competency framework to support CPD, and recruitment and appraisal processes, along with 'real' case studies.

www.ukmi.nhs.uk

The Primary and Community Care Pharmacy Network (PCCPN) has produced a competency framework to help support the understanding and development of community health services. www.pccpnetwork.org

Professional and regulatory bodies	
The Association of Professional Ambulance Personnel	www.apap.org.uk
The British Dietetic Association	www.bda.uk.com
British Orthoptic Society	www.orthoptics.org.uk
The Chartered Society of Physiotherapy	www.csp.org.uk
The College of Optometrists	www.college-optometrists.org
General Optical Council	www.optical.org
Health Professions Council	www.hpc-uk.org
Joint Royal Colleges Ambulance Liaison Committee	www.jrcalc.org.uk
Nursing and Midwifery Council	www.nmc-uk.org
Royal College of Nursing	www.rcn.org.uk
Royal Pharmaceutical Society of Great Britain	www.rpsgb.org.uk
The Society of Chiropodists and Podiatrists	www.feetforlife.org
The Society of Radiographers	www.sor.org
Department of Health guidance	www.dh.gov.uk

7 Glossary

Administer

To give a medicine by either introduction into the body, whether by direct contact with the body or not, (e.g. orally or by injection) or by external application (e.g. application of an impregnated dressing) [see section 130 Medicines Act 1968]

Black triangle medicine (▼)

Newly-introduced medicines still subject to special monitoring for potential side effects by the Medicines and Healthcare products Regulatory Agency (so-called because they are identified by a black triangle symbol)

Controlled drug

Narcotic drugs or other drugs liable to misuse which are subject to special controls under the Misuse of Drugs Act 1971

Dispense

To make up or give out a clinically appropriate medicine to a patient for self-administration or administration by another, usually a professional. In the case of prescription-only medicines, dispensing must be in response to a legally valid prescription. The act of dispensing is combined with advice about safe and effective use

General sales list (GSL) Medicine

A medicinal product that can be sold or supplied direct to the public in an unopened manufacturer's pack from any lockable business premises. Such products are listed in the Medicines Order 1984

Licensed indication

Treatment purpose for which a product may be used under the terms of the marketing authorisation granted by the Licensing Authority (**see also licensed medicine**)

Licensed medicine

A medicine which falls within the definition of a medicinal product and which is granted a marketing authorisation by the Licensing Authority when the safety, quality and efficacy of the product have been satisfactorily demonstrated by the license holder in accordance with EC directives 65/65

Marketing authorisation

The 1968 Medicines Act, which regulates the use of medicines in the UK, requires that a medicine must have a marketing authorisation (previously a product licence) before it can be used by the public. In the UK, marketing authorisations are granted by the Medicines and Healthcare products Regulatory Agency

Pharmacy (P) medicine

Any medicinal product other than those designated as GSL or POM products. Pharmacy medicines can be sold or supplied only from a registered pharmacy by or under the supervision of a pharmacist, subject to certain exceptions

Prescribe

To authorise in writing the supply of a medicine (usually but not necessarily a prescription-only medicine) for a named patient.

Prescription Only Medicines (POMs)

A medicinal product which may only be sold or supplied against the signed prescription of an appropriate practitioner i.e. doctor, dentist, or qualified and registered nurse, pharmacist, optometrist or allied health professional prescriber specified in the Prescription Only Medicines (Human Use) Order 1997

Summary of Product Characteristics (SPC)

The SPC forms an intrinsic and integral part of the Marketing Authorisation and is the basis of information for health professionals. It describes the properties and effects of the medicine, as well as warnings about it.

Supply

To provide a medicine to a patient/carer for administration*

- * There is no legal distinction between 'dispense' and 'supply' although there are considerable differences in practice. The act of dispensing includes supply and also encompasses a number of other cognitive functions (e.g. checking the validity of the prescription, the appropriateness of the medicine for an individual patient, assembly of the product). In common usage, 'dispense' is usually reserved to the activity of pharmacists and 'supply' can be used for nurses, pharmacists and other healthcare professionals.

